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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/909,567   | 07/20/2001  | Roberto A. Macina    | DEX-0214            | 4354             |
| 26259  | 7590        | 10/26/2004           | EXAMINER            |                  |
| LICATLA & TYRRELL P.C.<br>66 E. MAIN STREET<br>MARLTON, NJ 08053 |             |                      | SMITH, CAROLYN L    |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1631                |                  |

DATE MAILED: 10/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/909,567 | <b>Applicant(s)</b><br>MACINA ET AL. |  |
|                              | <b>Examiner</b><br>Carolyn L Smith   | <b>Art Unit</b><br>1631              |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 August 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

Applicant's amendments and remarks, filed 8/6/04, are acknowledged. Amended claim 1 is acknowledged.

Applicant's arguments, filed 8/6/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim 1 is herein under examination.

#### *Claim Rejections - 35 USC § 112, first paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is necessitated by amendment.

While it is plausible that SEQ ID NO: 12 may be over-expressed in lung cancer, there does not appear to be adequate written support that other polynucleotides from the claim 1, (c), limitation of "a polynucleotide with 97% identity to SEQ ID NO: 12 and which hybridizes under stringent conditions to the antisense sequence of SEQ ID NO:12" are over-expressed in lung

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cancer. This issue is particularly true since the above-mentioned quoted limitation encompasses oligomers that have 97% identity to SEQ ID NO: 12. The specification contains insufficient support for this broad limitation. This rejection is necessitated by amendment.

***Claims Rejected Under 35 U.S.C. § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. This rejection is necessitated by amendment.

Claim 1 recites the phrase "polynucleotide which [...] hybridizes under stringent conditions" which is vague and indefinite. It is unclear which criteria the applicants regard as stringent conditions (i.e. buffers, pH of buffer, etc.) or whether low, medium, or high stringency is meant. Applicants can resolve this issue by particularly pointing out the stringent conditions for which they have written support that are intended to allow the polynucleotide to hybridize. Clarification of the metes and bounds of the instant claim via clearer claim wording is requested.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sigma (1990) in view of *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594). This rejection is necessitated by amendment.

Sigma Catalog includes O 3003 (oligothymidylic acid, d[pT]<sub>4</sub>), which is an oligomer that matches 100% a segment of SEQ ID NO: 12 (nucleotide positions 575-578). The hybridization under stringent conditions in instant claim 1, (c), can reasonably be interpreted to be under low stringent conditions. Furthermore, claim 1, (c), recites "a polynucleotide with 97% identity to SEQ ID NO: 12" which supports the concept that subsequences, such as O 3003 (oligothymidylic acid, d[pT]<sub>4</sub>) and other short oligomers. Sigma does not describe the polynucleotide is over-expressed in lung cancer.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter that there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second paragraph, first full paragraph).

As Sigma describes an oligomer comprising the same structural properties as those recited in instant claim 1 (c), a skilled artisan would have been motivated to believe this composition would inherently include the characteristics of an identical composition, as stated in instant claim 1. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to realize identical compositions (i.e. O 3003 (oligothymidylic acid, d[pT]<sub>4</sub>), such as disclosed by Sigma) would have identical characteristics, as stated by *In re*

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*Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594). Thus, Sigma in view of *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594), motivate the instant invention. This rejection is necessitated by amendment.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

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1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

October 20, 2004

*Ardin H. Marschel* 10/22/04  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER